ClinicalEvidence

Varicose veins

Search date January 2010

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ABSTRACT

INTRODUCTION: Varicose veins are caused by poorly functioning valves in the veins, and decreased elasticity of the vein wall, allowing pooling of blood within the veins, and their subsequent enlargement. Varicose veins affect up to 40% of adults, and are more common in obese people, and in women who have had more than two pregnancies. METHODS AND OUTCOMES: We conducted a systematic review and aimed to answer the following clinical question: What are the effects of treatments in adults with varicose veins? We searched: Medline, Embase, The Cochrane Library and other important databases up to January 2010 (Clinical Evidence reviews are updated periodically, please check our website for the most up-to-date version of this review). We included harms alerts from relevant organisations such as the US Food and Drug Administration (FDA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA). RESULTS: We found 39 systematic reviews, RCTs, or observational studies that met our inclusion criteria. We performed a GRADE evaluation of the quality of evidence for interventions. CONCLUSIONS: In this systematic review we present information relating to the effectiveness and safety of the following interventions: compression stockings, endovenous laser, injection sclerotherapy, radiofrequency ablation, self-help (advice, avoidance of tight clothing, diet, elevation of legs, exercise), and surgery (stripping, avulsion, powered phlebectomy).

QUESTIONS

INTERVENTIONS

TREATMENTS

Likely to be beneficial

Unknown effectiveness

Footnote

*Categorisation based on consensus.

Key points

- Varicose veins are considered to be enlarged tortuous superficial veins of the leg.

  Varicose veins are caused by poorly functioning valves in the veins, and decreased elasticity of the vein wall, allowing pooling of blood within the veins, and their subsequent enlargement.

  Varicose veins affect up to 40% of adults and are more common in obese people, and in women who have had more than two pregnancies.

- Compression stockings are often used as first-line treatment for varicose veins, but we don't know whether they reduce symptoms compared with no treatment.

- Injection sclerotherapy may be more effective than compression stockings, but less effective than surgery, at improving symptoms and cosmetic appearance.

  We don't know which sclerotherapy agent is the best to use.

- Surgery (saphenofemoral ligation, stripping of the great saphenous vein, or avulsion) is likely to be beneficial in reducing recurrence, and improving cosmetic appearance, compared with sclerotherapy alone.

  We don't know whether stripping the great saphenous vein after saphenofemoral ligation improves outcomes compared with avulsion alone after ligation, or what the best method is for vein stripping.

  We found insufficient evidence on the effects of powered phlebectomy, radiofrequency ablation, endovenous laser, or self-help.

  However, endovenous procedures (radiofrequency ablation and endovenous laser) are increasingly used in mainstream clinical practice, and further evidence comparing them to other active treatments is emerging.

DEFINITION

Although we found no consistent definition of varicose veins, [1] it is commonly taken to mean enlarged tortuous subcutaneous veins. Any vein may become varicose, but the term "varicose veins" conventionally applies to the superficial veins of the leg, which may appear green, dark blue, or purple in colour. The condition is caused by poorly functioning (incompetent) valves within the veins and decreased elasticity of the vein walls, which allow deoxygenated blood to be pumped back to the heart, and to flow backward and pool in the superficial veins, causing them to enlarge and be-

come varicose. This often occurs in the saphenofemoral and saphenopopliteal junctions, and in the perforating veins that connect the deep and superficial venous systems along the length of the leg. The presence or absence of reflux caused by venous incompetence can be determined by clinical examination, handheld Doppler, or duplex ultrasound. Symptoms of varicose veins include pain, itching, limb heaviness, cramps, and distress about cosmetic appearance, although most lower limb symptoms may have a non-venous cause. [2] This review focuses on uncomplicated, symptomatic varicose veins. We have excluded treatments for chronic venous ulceration and other complications. We have also excluded studies that solely examine treatments for small, dilated veins in the skin of the leg, known as thread veins, spider veins, or superficial telangiectasia.

INCIDENCE/ PREVALENCE

One large US cohort study found the biannual incidence of varicose veins was 3% in women and 2% in men. [3] The prevalence of varicose veins in Western populations was estimated in one study to be about 25% to 30% in women and 10% to 20% in men. [4] However, a Scottish cohort study has found a higher prevalence of varices of the saphenous trunks and their main branches in men than in women (40% men *v* 32% women). [5] Other epidemiological studies have shown prevalence rates ranging from 1% to 40% in men, and 1% to 73% in women. [6]

AETIOLOGY/ RISK FACTORS

One cohort study found that parity with 3 or more births was an independent risk factor for development of varicose veins. [7] A further large case-control study found that women with two or more pregnancies were at increased risk of varicose veins, compared with women with one or no pregnancies (RR about 1.2–1.3 after adjustment for age, height, and weight). [3] It found that obesity was also a risk factor, although only in women (RR about 1.3). One narrative systematic review found insufficient evidence on the effects of other suggested risk factors, including genetic predisposition, prolonged sitting or standing, tight undergarments, low fibre diet, constipation, deep vein thrombosis, and smoking. [4] However, a large Danish population study found that prolonged standing or walking at work was an independent predictor of the need for varicose vein treatment. [8]

PROGNOSIS

We found no reliable data on prognosis, or on the frequency of complications, which include chronic inflammation of affected veins (phlebitis), venous ulceration, and bleeding rupture of varices.

AIMS OF INTERVENTION

To reduce symptoms, improve appearance, and prevent recurrence and complications, with minimal adverse effects.

OUTCOMES

Symptom improvement including pain, ache, itching, heaviness, cramps, and cosmetic distress or cosmetic appearance (self or physician rated). **Quality of life**. **Recurrence rates**. **Adverse effects** including complications of treatment, for example: haematoma formation; pigmentation; ulceration; superficial thrombophlebitis; and deep venous and pulmonary thromboembolism. Retreatment rates were considered only if other outcomes were unavailable, and are described only in the comments sections.

METHODS

Clinical Evidence search and appraisal January 2010. The following databases were used to identify studies for this systematic review: Medline 1966 to January 2010, Embase 1980 to January 2010, and The Cochrane Database of Systematic Reviews 2009, Issue 4 (1966 to date of issue). An additional search within The Cochrane Library was carried out for the Database of Abstracts of Reviews of Effects (DARE) and the Health Technology Assessment (HTA) database. We also searched for retractions of studies included in the review. Abstracts of the studies retrieved from the initial search were assessed by an information specialist. Selected studies were then sent to the contributor for additional assessment, using predetermined criteria to identify relevant studies. Study design criteria for inclusion in this review were: published systematic reviews of RCTs and RCTs in any language. RCTs had to be at least single blinded, and containing 20 or more individuals of whom 80% or more were followed up. There was no minimum length of follow-up required to include studies. We excluded all studies described as "open", "open label", or not blinded, unless blinding was impossible. We included systematic reviews of RCTs and RCTs where harms of an included intervention were studied applying the same study design criteria for inclusion as we did for benefits. In addition we use a regular surveillance protocol to capture harms alerts from organisations such as the US FDA and the UK MHRA, which are added to the reviews as required. To aid readability of the numerical data in our reviews, we round many percentages to the nearest whole number. Readers should be aware of this when relating percentages to summary statistics such as relative risks (RRs) and odds ratios (ORs). We have performed a GRADE evaluation of the quality of evidence for interventions included in this review (see table, p 20). The categorisation of the quality of the evidence (into high, moderate, low, or very low) reflects the quality of evidence available for our chosen outcomes in our defined populations of interest. These categorisations are not necessarily a reflection of the overall methodological quality of any individual study, because the *Clinical Evidence* population and outcome of choice may represent only a small subset of the

total outcomes reported, and population included, in any individual trial. For further details of how we perform the GRADE evaluation and the scoring system we use, please see our website (www.clinicalevidence.com).

QUESTION **What are the effects of treatments in adults with varicose veins?**

OPTION **COMPRESSION STOCKINGS**

Symptom improvement
Compared with no treatment Compression stockings may be more effective than no treatment at reducing pain scores, but we don't know whether they are more effective at improving itching, heaviness, leg swelling, night cramps, or preventing further development of varicose veins (very low-quality evidence).

Compared with injection sclerotherapy Compression stockings are less effective than sodium tetradecyl sulphate at 6 to 24 months at improving symptoms and cosmetic appearance of varicose veins in pregnant women with primary or recurrent varicose veins (moderate-quality evidence).

For GRADE evaluation of interventions for varicose veins, **see table, p 20 .**

Benefits:

Compression stockings versus no treatment:
We found one systematic review (search date 2008), which did not pool data and included 3 RCTs of sufficient quality. [9] The first crossover RCT (125 women with symptoms of chronic venous disease) included in the review compared class 1 (10–15 mmHg at the ankle) stockings versus a placebo stocking for 14 days. [9] The review reported that compression significantly reduced pain scores (measured by visual analogue scale) compared with placebo (absolute results not reported; P = 0.024). The review reported that other symptoms such as heaviness, cramps, and swelling of ankles also improved with compression stockings (further details and statistical analysis between groups not reported). In this RCT, results were based on 111/125 (88%) of people randomised, the method of randomisation was not described, allocation concealment was unclear, and the level of blinding at outcome assessment was not reported. The second RCT included in the review (42 pregnant women) compared class 1 stockings (18–21 mmHg), class 2 stockings (25–32 mmHg), and no stockings. [9] Women were stratified on the basis of presence or absence of varicose changes. The review reported that leg symptoms significantly improved in women wearing both types of compression stockings compared with control (absolute data not reported; P = 0.045), but there was no significant difference between groups in the occurrence of varicose veins (further details not reported; reported as no significant difference; P value not reported). The review reported that the method of randomisation was not described, allocation concealment was unclear, and analysis was not by intention to treat.

The third crossover RCT (72 people aged under 65 years with two or more of the following symptoms: pain, heaviness, itching, night cramps, swelling, or cosmetic distress) [10] included in the review [9] compared 4 treatments: a pharmacological agent (O-[beta-hydroxyethyl]-rutoside, 1 g/day orally); placebo alone; stockings plus placebo; and stockings plus the drug. The study did not specify the sites of venous incompetence. Each treatment was given for 4 weeks before crossover to another treatment. The RCT found no significant difference between stockings plus placebo and placebo alone for any symptom scores (66 people, measured on 100-point visual analogue scale: pain, P = 0.06; heaviness, P = 0.39; itching, P = 0.56; leg swelling, P = 0.13; night cramps, P = 0.24; see comment). [10] The RCT might have lacked power to detect clinically important effects.

Compression stockings versus injection sclerotherapy:
See benefits of injection sclerotherapy, p 4 .

Compression stockings versus surgery:
See benefits of surgery, p 8 .

Harms:

The review did not report on the harms of compression stockings. [9]

Comment:

Compression stockings versus no treatment:
The review that included both RCT and non-RCT evidence commented on the methodological flaws of many of the studies analysed. [9] The third crossover RCT did not report whether investigators were blinded to treatment allocation. [10] Reliability of results may be reduced because previous treatments might have continued to have effects, even after crossover. The study did not report the duration of any washout period, which might have reduced such an effect between treatment periods.

Clinical guide:
Compression stockings are often used as first-line treatment for varicose veins in primary care. There is no good evidence that this is beneficial in terms of slowing progression of venous disease although it may control some symptoms. Further RCTs are unlikely to be undertaken.

OPTION INJECTION SCLEROTHERAPY

Symptom improvement
Injection sclerotherapy compared with no treatment or conservative treatment Injection sclerotherapy may be more effective at reducing the proportion of people reporting aching and cosmetic concerns, but we don't know whether it is more effective at reducing heaviness, itching, or swelling at 1 year (very low-quality evidence).

Injection sclerotherapy compared with compression stockings Sodium tetradecyl sulphate is more effective at 6 to 24 months at improving symptoms and cosmetic appearance of varicose veins in pregnant women with primary or recurrent varicose veins (moderate-quality evidence).

Sclerotherapy plus ligation compared with conventional surgery or sclerotherapy alone Sclerotherapy plus ligation is more effective than sclerotherapy alone, but less effective than conventional surgery, at improving cosmetic appearances of varicose veins as judged by both surgeons and participants at 3 years (moderate-quality evidence).

Sclerotherapy plus ligation compared with stripping plus ligation Sclerotherapy plus ligation is less effective at improving cosmetic appearances as judged by both surgeon and participant at 3 years (moderate-quality evidence).

Foam sclerotherapy plus saphenofemoral ligation compared with saphenofemoral ligation plus stripping plus avulsion or conventional stripping/invagination stripping Reverse foam sclerotherapy plus saphenofemoral ligation may be more effective than conventional or invagination stripping plus saphenofemoral ligation (results combined in analysis) at reducing the need for analgesia and the extent of thigh bruising at 14 days, but we don't know about other symptoms or in the longer term (very low-quality evidence).

Different types of sclerosant compared with each other We don't know whether any one sclerosant is consistently more effective than any other sclerosant at improving symptoms as we found insufficient evidence (very low-quality evidence).

Recurrence rates
Compared with surgery We don't know whether sclerotherapy is more effective at reducing recurrence rates (very low-quality evidence).

Foam sclerotherapy compared with conventional sclerotherapy We don't know whether foam sclerotherapy is more effective at reducing the incidence of new varicose veins (moderate-quality evidence).

Quality of life
Foam sclerotherapy plus saphenofemoral ligation compared with saphenofemoral ligation plus stripping plus avulsion or conventional stripping/invagination stripping Ligation plus foam sclerotherapy seems to be more effective than ligation plus stripping plus avulsions at improving quality of life scores (as measured by Aberdeen Varicose Vein Questionnaire) at 3 months (moderate-quality evidence).

For GRADE evaluation of interventions for varicose veins, see table, p 20 .

Benefits:

Injection sclerotherapy versus no treatment or conservative treatment:
We found one systematic review [1] and one subsequent RCT. [11] The systematic review (search date 2006) identified no RCTs. The subsequent RCT (34 participants with minor below-knee varicose veins without reflux, but with symptoms of aching or cosmetic concerns) compared injection sclerotherapy with sodium tetradecyl sulphate versus conservative treatment. The conservative treatment included advice on wearing support stockings, exercise, ideal weight, and effects of work and pregnancy on varicose veins. The injection sclerotherapy was followed by compression using foam pads and a class II graduated compression stocking or bandage all the way up the leg from the foot. The RCT found that injection sclerotherapy significantly reduced the proportion of people reporting aching and cosmetic concerns compared with conservative treatment after 1 year (aching: 69% with sclerotherapy *v* 28% with conservative treatment; P <0.05; cosmetic concerns: 84% with sclerotherapy *v* 14% with conservative treatment; P <0.05). The RCT found no significant difference between injection sclerotherapy and conservative treatment in reduction of heaviness, itching, or swelling at 1 year (heaviness: 84% with sclerotherapy *v* 43% with conservative treatment; itching: 84% with sclerotherapy *v* 50% with conservative treatment; swelling: 84% with sclerotherapy *v* 57% with conservative treatment; P values reported as not significant). [11]

Injection sclerotherapy versus compression stockings:
One systematic review (search date 2006) found one RCT (101 pregnant women with primary or recurrent varicose veins), which compared sclerotherapy using sodium tetradecyl sulphate versus compression stockings. [1] It found that sclerotherapy significantly improved symptoms and cosmetic appearance compared with compression stockings after 6 to 24 months (improved symptoms and cosmetic appearance: 43/44 [98%] with sclerotherapy *v* 17/28 [61%] with compression stockings; RR 1.61, 95% CI 1.19 to 2.18).

Injection sclerotherapy versus surgery:
We found one systematic review (search date 2004, 6 RCTs) [12] and one subsequent RCT [13] comparing sclerotherapy versus surgery. The review did not conduct a meta-analysis of the results of the RCTs because of heterogeneity of the data. The first RCT identified by the review (164 people with symptomatic primary varicose veins, aged 21–65 years) compared injection sclerotherapy (polidocanol 30 mg/mL; 0.5–0.75 mL injected into each varicosity, repeated after 1–2 weeks if required) versus surgery. [14] Participants were allocated to treatments without regard to site of venous incompetence (53 legs with saphenofemoral or saphenopopliteal incompetence alone; 97 legs with saphenofemoral or saphenopopliteal incompetence combined with perforator incompetence; 17 legs with perforator incompetence only). Among people allocated to surgery, the surgical technique depended on the site of venous incompetence (see comment below). The RCT found that surgery increased the proportion of people who were free of varicose veins at 5 years compared with injection sclerotherapy (AR for freedom from varicose vein at 5 years: 3% with sclerotherapy *v* 55% with surgery; significance not reported; see comment below).

The second RCT identified by the review (249 people with varicose veins, but no previous treatment, aged 15–64 years) compared injection sclerotherapy versus surgery. [15] The study did not specify the proportions of people with saphenofemoral, saphenopopliteal, or perforator incompetence. The extent and type of surgery depended on the site of venous incompetence (see comment below). The trial did not report on symptoms, quality of life, or recurrence (see comment below).

The third RCT identified by the review (82 people aged over 18 years) compared sclerotherapy (3% polidocanol; repeat treatments at 2 or 4 weeks, or both, as necessary) versus avulsion under local anaesthetic. [16] People with saphenofemoral or deep venous incompetence were excluded. Sclerotherapy was significantly less effective in reducing recurrence at 1 and 2 years compared with avulsion (AR for recurrence at 1 year: 25% with sclerotherapy *v* 2% with avulsion; RR 12, 95% CI 1.62 to 88.7; AR for recurrence at 2 years: 38% with sclerotherapy *v* 2% with avulsion; RR 18, 95% CI 2.5 to 129.5).

The fourth RCT identified by the review (887 people with long saphenous vein incompetence, with or without perforator incompetence; see above) compared 6 treatments: standard-dose conventional sclerotherapy (148 people); high-dose conventional sclerotherapy (136 people); foam sclerotherapy (150 people); ligation (155 people); stab avulsion (144 people); and combined ligation and high-dose conventional sclerotherapy (154 people). [17] Avulsion or ligation with or without sclerotherapy reduced the incidence of new varicose veins at 5 and 10 years compared with sclerotherapy alone, although it was not clear whether differences were significant (AR for new varicose veins at 5 years: 48% with standard-dose sclerotherapy *v* 41% with high-dose sclerotherapy *v* 44% with foam sclerotherapy *v* 34% with ligation *v* 40% with stab avulsion *v* 37% with ligation plus sclerotherapy; AR for new varicose veins at 10 years: 56% with standard-dose sclerotherapy *v* 49% with high-dose sclerotherapy *v* 51% with foam sclerotherapy *v* 38% with ligation *v* 41% with stab avulsion *v* 37% with ligation plus sclerotherapy; significance not reported for any outcome).

The fifth RCT identified by the review (516 people with primary varicose veins) compared 3 treatments: conventional long or short saphenous surgery under general anaesthetic (161 people); local anaesthetic ligation of the saphenofemoral or saphenopopliteal junctions followed by injection sclerotherapy (165 people); and injection sclerotherapy with 3% aethoxysklerol (137 people). [18] It found that conventional surgery significantly improved objective outcomes (appearance of varicose veins, as judged by the surgeon) and subjective outcomes (appearance of varicose veins, as judged by the participant) compared with ligation plus sclerotherapy at 3 years ($P < 0.0005$). It also found that ligation plus sclerotherapy significantly improved objective and subjective outcomes compared with sclerotherapy alone at 3 years ($P < 0.0005$).

The sixth RCT identified by the review (156 people with primary long saphenous vein incompetence, 181 limbs) compared ligation plus stripping of the long saphenous vein to the ankle (78 people, 89 limbs) versus ligation plus sclerotherapy using 1% aethoxysklerol (78 people, 92 limbs). [19] It found that ligation plus stripping significantly improved both subjective cosmetic appearance (as judged by the participant) and objective cosmetic appearance (as judged by the surgeon) compared with ligation plus sclerotherapy at 3 years (subjective improvement: 72% with surgery *v* 54% with sclerotherapy; $P < 0.05$; objective improvement: 61% with surgery *v* 39% with sclerotherapy; $P < 0.05$).

Foam sclerotherapy plus saphenofemoral ligation versus saphenofemoral ligation plus stripping plus avulsion or conventional stripping/invagination stripping:
We found one RCT comparing local anaesthetic saphenofemoral ligation combined with ultrasound guided foam sclerotherapy versus saphenofemoral ligation plus stripping plus avulsion. [13] It found that ligation plus foam sclerotherapy significantly reduced time to return to normal activity compared with ligation plus stripping plus avulsions (60 people with primary great saphenous varicose veins; median time to return to normal activity: 2 days with ligation plus sclerotherapy *v* 8 days with ligation plus stripping plus avulsions; P <0.001). At 3 months, ligation plus foam sclerotherapy significantly improved quality of life compared with ligation plus stripping plus avulsions (assessed using the Aberdeen Varicose Vein Questionnaire [higher score = worse quality of life]; decrease in median score: 46% with ligation plus sclerotherapy *v* 40% with ligation plus stripping plus avulsions; P <0.001).

A further RCT of 82 people (90 limbs) with symptomatic varicose veins undergoing saphenofemoral ligation compared reverse foam sclerotherapy, conventional stripping, and invagination stripping. [20] The RCT reported that, compared with the other two techniques, significantly fewer people required analgesia at 14 days in the reverse foam sclerotherapy group (results presented graphically; P <0.001), and there was significantly less thigh bruising reported by patients or observers in the reverse foam sclerotherapy group (classified as none, moderate, or significant: patient assessed, P = 0.005; observer assessed, P <0.001; absolute numbers not reported). The RCT did not report results beyond 14 days. [20]

Different types of sclerosant versus each other:
See glossary. One systematic review (search date 2006) found no RCTs reporting clinical outcomes in people with varicose veins. [1] We found two subsequent RCTs. [21] [22] The first subsequent double-blind RCT (87 people with a total of 109 varicose veins; 55 veins 1–3 mm diameter; 54 veins 3–6 mm diameter) excluded people with saphenofemoral or saphenopopliteal incompetence. [21] Each vein, rather than each person, was randomly allocated to injection sclerotherapy with either polidocanol or sodium tetradecyl sulphate. The strength of solution depended on the size of the vein being treated (veins 1–3 mm diameter: polidocanol 1% or sodium tetradecyl sulphate 0.5%; veins 3–6 mm diameter: polidocanol 3% or sodium tetradecyl sulphate 2%). The RCT found no significant difference between polidocanol and sodium tetradecyl sulphate in change in photographic appearance (assessed by 3 blinded vascular surgeons) of either size group of veins 16 weeks after treatment (scale of 1–5 [1 = worse than pretreatment photograph; 5 = complete disappearance]; mean score for veins 1–3 mm diameter: 4.6 with sodium tetradecyl sulphate *v* 4.4 with polidocanol; P = 0.83; mean score for veins 3–6 mm diameter: 4.5 with sodium tetradecyl sulphate *v* 4.7 with polidocanol; P = 0.58). The second subsequent RCT (1622 people) compared 3 treatments: polidocanol, sodium tetradecyl sulphate, and polidocanol plus sodium tetradecyl sulphate. [22] It found that more people taking polidocanol plus sodium tetradecyl sulphate had improved symptoms (night cramps, pains, fatigue, and heaviness) and that fewer people had oedema compared with polidocanol or sodium tetradecyl sulphate alone, at 5 years (symptoms: 211/306 [69%] with polidocanol *v* 277/380 [73%] with sodium tetradecyl sulphate *v* 180/228 [79%] with polidocanol plus sodium tetradecyl sulphate; significance not reported; oedema: 185/304 [61%] with polidocanol *v* 123/152 [64%] with sodium tetradecyl sulphate *v* 27/36 [74%] with polidocanol plus sodium tetradecyl sulphate; significance not reported). The method of randomisation was not reported, and allocation concealment and level of blinding was unclear. The RCT took place over a 10-year period (1991–2000), and it was not clear whether some of the outcomes were patient or investigator assessed. [22]

Foam sclerotherapy versus conventional sclerotherapy:
We found two RCTs. [17] [23] The first RCT (887 people with uncomplicated varicose veins and great saphenous vein incompetence, with or without perforator incompetence) compared 6 treatment arms: standard-dose conventional sclerotherapy (1–2 mL 2% or 3% sodium tetradecyl sulphate according to vein calibre, with 2–3 weeks' compression after sclerotherapy); high-dose conventional sclerotherapy (3–6 mL 3% sodium tetradecyl sulphate, with 1–2 weeks' compression); foam sclerotherapy (foaming agent plus 3% sodium tetradecyl sulphate); ligation; stab avulsion; and ligation plus sclerotherapy. [17] The RCT found that the incidence of new varicose veins was similar with foam sclerotherapy, standard-dose conventional sclerotherapy, and high-dose conventional sclerotherapy at 5 and 10 years (AR for new veins at 5 years: 48% with standard-dose sclerotherapy *v* 41% with high-dose sclerotherapy *v* 44% with foam sclerotherapy; AR for new veins at 10 years: 56% with standard-dose sclerotherapy *v* 49% with high-dose sclerotherapy *v* 51% with foam sclerotherapy; significance not reported). The second RCT (88 people with great saphenous vein incompetence) compared sclerotherapy with 3% polidocanol foam versus 3% polidocanol liquid. [23] The RCT did not report on clinical outcomes other than harms (see harms below).

Harms:

Injection sclerotherapy versus no treatment or conservative treatment:
The subsequent RCT found that more people receiving sclerotherapy than conservative treatment had phlebitis (2/13 [15%] with sclerotherapy *v* 1/15 [7%] with conservative treatment; P value not reported). [11] The RCT also reported staining in 6/13 (46%) of the sclerotherapy group. One person (8%) receiving injection sclerotherapy reported blistering at the injection site.

Injection sclerotherapy versus compression stockings:
The systematic review gave no information on adverse effects. [1]

Injection sclerotherapy versus surgery:
The first RCT identified by the review reported postoperative wound infection in 6% and symptoms of sural or saphenous nerve injury in 10% of surgically treated participants (rates not reported in the sclerotherapy group). [14] Five people (proportion not reported) in the sclerotherapy group had migratory thrombophlebitis and 28% developed haematoma (rates not reported for surgical group). Duration of sick leave was greater with surgery than with sclerotherapy (mean duration: 20 days with surgery *v* 1 day with sclerotherapy; significance not reported). One person in the surgical arm had a symptomatic pulmonary embolism that resolved without complications. No thromboembolic events occurred in the sclerotherapy group. The second RCT reported that one person in the surgically treated group had severe bronchospasm under anaesthetic. [15] The 5-year follow-up to this study reported that during surgery one person had a myocardial infarction and one person had a pulmonary embolus. [24] The third RCT found no significant difference in phlebitis between avulsion and sclerotherapy at 2 weeks (12% with avulsion *v* 27% with sclerotherapy; P = 0.07). [16] Sclerotherapy reduced telangiectasia (thread veins) at 2 years compared with avulsion (6% with avulsion *v* 0% with sclerotherapy; P = 0.039). The fourth RCT did not discuss harms. [17] The fifth RCT reported one pulmonary embolus with conventional surgery (significance not reported). [18] There was no significant difference between treatments in minor complication rates (details of complications not reported; reported as not significant; P value not reported). The sixth RCT found saphenous nerve injury in 27 limbs (33%) with surgery compared with 0% with sclerotherapy (significance not reported). [19] The subsequent RCT found no difference in early complication rates between ligation plus foam sclerotherapy and ligation plus stripping and avulsions (7/30 [23%] in both groups; difference reported as not significant). [13] At 3 months, 5 people in the ligation plus foam sclerotherapy group (17%) had resolving skin pigmentation, whereas 3 (10%) had had an episode of thrombophlebitis. Three people (9%) in the ligation plus stripping plus avulsions group had evidence of saphenous nerve injury, and one person (3%) had a skin ulcer (statistical assessments for complications at 3 months not performed).

Foam sclerotherapy plus saphenofemoral ligation versus saphenofemoral ligation plus stripping plus avulsion or conventional stripping/invagination stripping:
The RCT stated that no clinically detectable adverse effects attributable to foam sclerotherapy were reported during the follow-up period. [20]

Different types of sclerosant:
The first subsequent RCT only reported local reactions. [21] It found that both treatments were associated with similar rates of ecchymosis, hyperpigmentation, and thrombosis (ecchymosis: 70% of veins treated with sodium tetradecyl sulphate *v* 58% with polidocanol; hyperpigmentation: 64% with sodium tetradecyl sulphate *v* 53% with polidocanol; thrombosis: 46% with sodium tetradecyl sulphate *v* 42% with polidocanol; significance not reported). Polidocanol reduced local urticaria and skin necrosis compared with sodium tetradecyl sulphate (skin necrosis: 7% with sodium tetradecyl sulphate *v* 0% with polidocanol; urticaria: 36% with sodium tetradecyl sulphate *v* 23% with polidocanol; significance not reported). The second subsequent RCT found that sodium tetradecyl sulphate caused more local necrosis, hyperpigmentation, and telangiectasia compared with polidocanol or polidocanol plus sodium tetradecyl sulphate combination treatment (absolute figures and significance data for the between group comparison not reported). [22]

Foam sclerotherapy versus conventional sclerotherapy:
The first RCT did not discuss harms. [17] The second RCT found similar rates of skin inflammation with polidocanol foam and with polidocanol liquid (2/45 [4%] with foam *v* 3/43 [7%] with liquid; P value not reported). [23]

Comment:

Injection sclerotherapy versus no treatment or conservative treatment:
The conservative treatment group in the subsequent RCT [11] included advising participants to consider wearing grade I to III support stockings. It is not clear how many participants did this.

Injection sclerotherapy versus surgery:
The effects of surgery versus injection sclerotherapy or other treatments may vary according to the sites of venous incompetence. Some RCTs included in the systematic review failed to report the relative effects with regard to sites of venous incompetence. Only two RCTs included in the

systematic review were judged by the review to be of sufficient quality. In the surgical groups of the first two RCTs, varicose veins from saphenofemoral or saphenopopliteal incompetence were treated by ligation and stripping, whereas incompetent perforator veins were treated by avulsion. [14] [15] The first RCT did not report whether the investigators were blinded to treatment allocation. [14] It was also not clear whether analysis was by intention to treat.

Foam sclerotherapy plus saphenofemoral ligation versus saphenofemoral ligation plus stripping plus avulsion or conventional stripping/invagination stripping:
One RCT found that 4 people (13%) in the ligation plus foam sclerotherapy group needed a repeat treatment to deal with residual varicose veins. [13]

Different types of sclerosant:
The first subsequent RCT also included a further 42 people with telangiectasia (veins less than 1 mm diameter). [21] These were excluded from the results.

Foam sclerotherapy:
We found one systematic review, which included 69 studies and pooled data (including RCTs; registry reports; comparative studies; case series; case reports; or published abstract-only or unpublished studies). [25] Of these, there were 8 published RCTs and two further RCTs in conference abstracts. The methodological quality of the RCTs was reported as poor by the review. [25] We have not reported this further as studies looking at treatment of telangiectasias were included, some analysis included observational data, and the review reported on occlusion of treated veins, which is a surrogate outcome not reported in this *Clinical Evidence* review.

Clinical guide:
There is little evidence for the use of (liquid) injection sclerotherapy in treatment of symptomatic varicose veins with demonstrated reflux. Most clinicians would consider using this as an adjunctive treatment to other procedures, for example for residual varicose veins following surgery. Foam sclerotherapy is increasingly used in clinical practice. Foam plus saphenofemoral ligation seems to confer benefit over stripping. There is no evidence to support the use of foam as a replacement for conventional surgery.

OPTION SURGERY (AVULSION)

Symptom improvement
Compared with ligation plus sclerotherapy Conventional surgery is more effective at improving cosmetic appearances of varicose veins as judged by both surgeons and participants at 3 years (moderate-quality evidence).

Compared with powered phlebectomy We don't know whether avulsion is more effective at reducing pain at 8 days or at improving cosmetic appearance at 6 weeks (low-quality evidence).

Recurrence rates
Compared with sclerotherapy We don't know whether avulsion is more effective at reducing recurrence rates (very low-quality evidence).

Avulsion plus stripping compared with avulsion alone We don't know whether avulsion of the long saphenous vein to the knee is more effective at reducing recurrence rates (low-quality evidence).

Quality of life
Avulsion plus stripping plus saphenofemoral ligation compared with injection sclerotherapy (foam sclerotherapy) plus saphenofemoral ligation Avulsion plus stripping plus saphenofemoral ligation is less effective at improving quality of life scores and at reducing time to return to normal activities (moderate-quality evidence).

Note
We found no clinically important results about avulsion compared with no treatment or compression stockings in people with varicose veins. There is consensus that avulsion is likely to be beneficial for the treatment of varicose veins.

For GRADE evaluation of interventions for varicose veins, see table, p 20 .

Benefits:

Avulsion versus no treatment:
We found no RCTs that compared surgery versus no treatment.

Avulsion versus compression stockings:
We found no RCTs that compared surgery versus compression stockings.

Avulsion versus injection sclerotherapy:
See benefits of injection sclerotherapy, p 4 .

Avulsion plus stripping versus avulsion alone:
We found two RCTs that compared avulsion plus stripping of the great saphenous vein to the knee following saphenofemoral ligation versus avulsion of the long saphenous vein alone following ligation. [26] [27] The first RCT (69 people, 89 legs randomised, followed up for a median of 21 months) found that avulsion plus stripping to the knee significantly decreased clinical recurrence and significantly increased participant satisfaction compared with avulsion alone (clinical recurrence: 28/43 [65%] with avulsion plus stripping *v* 8/46 [17%] with avulsion; P <0.001; proportion of legs rated as "successfully treated": 28/43 [65%] with avulsion plus stripping *v* 17/46 [37%] with avulsion; P <0.05). [26] The second RCT (100 people randomised, 133 legs treated) found no significant difference between treatments in recurrence or participant satisfaction at 5 years (legs free of recurrence: 32/52 [61%] with avulsion plus stripping *v* 28/58 [48%] with avulsion; RR 1.28, 95% CI 0.91 to 1.82; participants "satisfied": 35/39 [90%] with avulsion plus stripping *v* 30/39 [77%] with avulsion; RR 1.17, 95% CI 0.95 to 1.42). [27] The second RCT had later results published in a subsequent paper although the follow-up of 51% falls below our inclusion limit. [28] The extension of the second RCT found no significant difference between avulsion plus stripping and avulsion alone in recurrence of varicose veins after 11 years (absolute numbers not reported; P value reported as not significant.) [28]

Avulsion versus powered phlebectomy:
See benefits of powered phlebectomy, p 13 .

Harms:

Surgery versus no treatment:
We found no RCTs.

Surgery versus compression stockings:
We found no RCTs.

Surgery versus injection sclerotherapy:
See harms of injection sclerotherapy, p 4 .

Avulsion plus stripping versus avulsion:
The RCTs did not report on harms. [26] [27] [29]

Stripping versus sequential avulsion:
See harms of stripping, p 9 .

Avulsion versus powered phlebectomy:
See harms of powered phlebectomy, p 13 .

Comment:

Avulsion versus injection sclerotherapy:
See comment under injection sclerotherapy, p 4 .

Clinical guide:
Most clinicians believe that, following saphenofemoral ligation, stripping to the knee plus avulsion is the first-line treatment for primary great saphenous varicose veins. Newer treatments for varicose veins such as foam sclerotherapy, radiofrequency ablation, or endovenous laser should be compared with surgery in well-designed RCTs. There is no evidence for any benefit for powered phlebectomy over avulsions of varicose veins.

OPTION SURGERY (STRIPPING)

Symptom improvement
Stripping plus ligation compared with sclerotherapy plus ligation Stripping plus ligation is more effective at improving cosmetic appearances as judged by both surgeon and participant at 3 years (moderate-quality evidence).

Stripping compared with injection sclerotherapy Conventional or invagination stripping plus saphenofemoral ligation (results combined in analysis) may be less effective than reverse foam sclerotherapy plus saphenofemoral ligation at reducing the need for analgesia and the extent of thigh bruising at 14 days, but we don't know about other symptoms or in the longer term (very low-quality evidence).

Stripping compared with sequential avulsion Avulsion plus stripping may be no more effective at improving daily activity scores and may be more painful at 1 week (low-quality evidence).

Partial stripping compared with total stripping We don't know whether partial stripping is more effective at improving symptoms but it may reduce the incidence of saphenous nerve damage (very low-quality evidence).

Inversion stripping compared with conventional stripping Inversion stripping of the long saphenous vein is more effective at reducing pain scores at 1 week in people with primary long saphenous varicose veins (moderate-quality evidence).

Cryostripping compared with conventional stripping We don't know whether cryostripping is more effective at reducing pain, night cramps, oedema, and visibility of varicose veins at 28 days (low-quality evidence).

Local anaesthetic flush after conventional stripping compared with conventional stripping alone Local anaesthetic flush of the long saphenous vein tunnel after stripping is more effective at reducing postoperative pain and haematoma formation at 6 weeks (moderate-quality evidence).

Stripping compared with ambulatory conservative haemodynamic management of varicose veins (CHIVA) The CHIVA technique may be more effective than ligation of the saphenofemoral junction and stripping at improving objective outcomes (measured by assessors using the Hobbs score), but may be no more effective than ligation of the saphenofemoral junction and stripping at improving subjective outcomes assessed by patients (low-quality evidence).

Cryostripping compared with endovenous laser Cryostripping may be less effective than endovenous laser at reducing pain scores (measured by visual analogue scale) at 10 days. We don't know whether cryostripping is more effective than endovenous laser at improving outcomes measured by the Venous Clinical Severity Score at 6 months to 2 years (low-quality evidence).

Stripping compared with endovenous laser We don't know whether saphenofemoral ligation plus stripping plus avulsions is more effective than endovenous laser at improving pain, cosmetic appearance, or outcomes measured by Venous Clinical Severity Score between 7 days and 6 months (low-quality evidence).

Recurrence rates

Adding stripping to avulsion compared with avulsion alone We don't know whether avulsion of the long saphenous vein to the knee is more effective at reducing recurrence rates (low-quality evidence).

Quality of life

Stripping versus injection sclerotherapy Ligation plus stripping plus avulsions seems to be less effective than ligation plus foam sclerotherapy at improving quality of life scores (as measured by Aberdeen Varicose Vein Questionnaire) at 3 months (moderate-quality evidence).

Cryostripping compared with conventional stripping We don't know whether cryostripping is more effective than conventional stripping at improving quality of life scores (as measured by 8 domains of the short-form [SF]-36 questionnaire) at 6 months (very low-quality evidence).

Cryostripping compared with endovenous laser We don't know whether cryostripping is more effective than endovenous laser at improving quality of life scores (as measured by the Aberdeen Varicose Vein Symptom Score) at 6 months to 2 years (low-quality evidence).

Stripping compared with endovenous laser We don't know whether saphenofemoral ligation plus stripping plus avulsions is more effective than endovenous laser at improving quality of life scores (measured by the Chronic Venous Insufficiency Quality of Life Questionnaire or the Aberdeen Varicose Vein Symptom Score) at 4 weeks to 6 months (low-quality evidence).

Note

We found no clinically important results comparing stripping (partial or total, with or without avulsion) with no treatment or compression stockings in the treatment of people with varicose veins. There is consensus that stripping is likely to be beneficial for the treatment of varicose veins.

For GRADE evaluation of interventions for varicose veins, **see table, p 20 .**

Benefits:

Stripping versus no treatment:
We found no RCTs that compared stripping versus no treatment (see comment below).

Stripping versus compression stockings:
We found no RCTs that compared stripping versus compression stockings.

Stripping versus injection sclerotherapy:
See benefits of injection sclerotherapy, p 4 .

Adding stripping to avulsion versus avulsion alone:
See benefits of avulsion, p 8 .

Stripping versus sequential avulsion:
We found one RCT (80 people with primary saphenofemoral varicose veins) comparing stripping of the long saphenous vein to the knee plus avulsion after saphenofemoral ligation versus avulsion of the long saphenous vein after ligation. [29] There was a technical procedure failure in 5 people in the stripping group and two people in the sequential avulsion group. [29] It found that avulsion plus stripping significantly increased pain (assessed using a linear analogue pain scale from 0–10) compared with avulsion after 1 week (results presented graphically; P <0.001). It found no significant difference between treatments in daily activity scores (score range 0–7) at 1 week (results presented graphically; reported as not significant; P value not reported).

Partial stripping versus total stripping:
We found one RCT (163 people), which compared partial stripping of the long saphenous vein to the knee following saphenofemoral ligation versus total stripping to the ankle following ligation. [30] It found similar improvements in clinical outcome with both treatments (clinician assessed using the Haegers classification system, where excellent = no symptoms and no residual varices, good = no symptoms but residual varices, fair = persisting symptoms and varices, poor = no improvement in symptoms and large persistent varices; treatment rated as excellent or good: 97% with partial stripping *v* 94% with total stripping; P value not reported).

Inversion stripping versus conventional stripping:
We found one RCT (30 people with primary great saphenous varicose veins), which compared inversion stripping of the long saphenous vein following saphenofemoral ligation versus conventional stripping following ligation. [31] It found that inversion stripping significantly reduced pain scores (assessed on a visual analogue scale, where 0 = no pain and 5 = severe pain) compared with conventional stripping at 1 week (mean visual analogue scale score: 9.5 with conventional stripping *v* 5.5 with inversion stripping; P = 0.02).

Cryostripping versus conventional stripping:
We found two RCTs comparing cryostripping with conventional stripping. [32] [33] The first RCT (40 people with primary great saphenous varicose veins) found no significant difference between cryostripping (cryosurgery) and conventional stripping in pain during the day, night cramps, oedema, and visibility of varicose veins after 28 days (absolute figures not reported; P value reported as not significant). [32] The second RCT (160 people with primary great saphenous varicose veins) compared conventional stripping versus cryostripping and assessed quality of life (measured by 8 domains of the short-form [SF]-36 questionnaire). [33] The RCT found no significant difference between groups in any of the 8 domains at 6 months, although both groups improved significantly compared with baseline (reported as no significant difference between groups; P value not reported). [33] Results were based on 146/160 (91%) of people randomised, with two people with conventional stripping and 6 people with cryostripping being excluded from the analysis as the surgeon considered the stripping had been unsuccessful or incomplete.

Local anaesthetic flush after conventional stripping versus conventional stripping alone:
We found one RCT (100 people with primary varicose veins secondary to great saphenous vein incompetence), which compared using 20 mL of 0.25% bupivacaine to flush the long saphenous vein tunnel after conventional stripping versus using 20 mL of normal saline. [34] The RCT looked at postoperative pain over 6 weeks, using a visual analogue score of 0 to 10, analgesic intake measured in number of times taken in the first week postoperatively, and proportion of people with haematoma formation. It found that local anaesthetic flush of the great saphenous vein tunnel after stripping significantly reduced postoperative pain over 6 weeks, analgesic intake over 1 week, and haematoma formation (median postoperative pain visual analogue score: 6.8 with local anaesthetic *v* 26 with saline; P <0.001; median analgesic intake over 1 week: 6.5 with local anaesthetic *v* 18 with saline; P <0.001; haematoma formation: 3/50 [6%] with local anaesthetic *v* 12/50 [24%] with saline; P = 0.007). [34]

Stripping versus ambulatory conservative haemodynamic management of varicose veins (CHIVA):
We found one RCT (150 people with primary great saphenous varicose veins), which compared ligation of the saphenofemoral junction and stripping to the haemodynamic CHIVA technique, which involves saphenofemoral ligation and targeted division of incompetent tributaries. [35] Results were based on 124/150 (82%) people randomised. Objective outcomes were assessed by blinded assessors using the Hobbs score (score 1: no visible/palpable veins; score 2: few visible/palpable veins, diameter <5 mm; score 3: remaining or newly formed varicose veins, diameter >5 mm; score 4: incompetent main trunks and perforator). Subjective scores were patient assessed by a 4-point scoring system (score 1: no inconvenience; score 2: slight functional or cosmetic imperfection, satisfied; score 3: appreciable functional/cosmetic failure, dissatisfaction; score 4: unaltered or increased inconvenience). The RCT found that CHIVA significantly improved outcomes when measured objectively by medical assessors (mean: 2.2 with stripping *v* 1.9 with CHIVA; P <0.038), but

found no significant difference between groups in subjective outcome assessed by patients (mean: 1.65 with stripping *v* 1.81 with CHIVA; reported as not significant; P value not reported). [35]

Cryostripping versus endovenous laser:
See benefits of endovenous laser, p 15 .

Stripping versus endovenous laser:
See benefits of endovenous laser, p 15 .

Harms:

Stripping versus no treatment:
We found no RCTs that compared stripping versus no treatment.

Avulsion versus compression stockings:
We found no RCTs that compared stripping versus compression stockings.

Stripping versus sequential avulsion:
The RCT found that 3 people experienced minor sensory loss in the saphenous nerve distribution after treatment (2/40 [5%] with stripping *v* 1/40 [3%] with sequential avulsion; significance not reported). [29] It also found that stripping significantly increased bruising compared with sequential avulsion (median area of bruising: 160 cm^2 with stripping *v* 56 cm^2 with sequential avulsion; P <0.01).

Surgery versus injection sclerotherapy:
See harms of injection sclerotherapy, p 4 .

Adding stripping to avulsion versus avulsion alone:
See harms of avulsion, p 8 .

Partial stripping versus total stripping:
The RCT found that partial stripping to the knee significantly reduced the incidence of saphenous nerve damage compared with total stripping to the ankle (5/77 [7%] with partial stripping *v* 31/80 [39%] with total stripping; P <0.001). [30]

Inversion stripping versus conventional stripping:
The RCT found no significant difference between treatments in bruising after 1 week (median area: 137.5 cm^2 with inversion stripping *v* 195.5 cm^2 with conventional stripping; P = 0.08). [31]

Cryostripping versus conventional stripping:
One RCT found that cryostripping significantly increased postoperative pain scores (numerical rating scale) compared with conventional stripping after 5 days (1.7 with cryostripping *v* 3.3 with conventional stripping; P = 0.04). [32] However, it found no significant difference between cryostripping and conventional stripping in postoperative pain scores on the other postoperative days (up to 28 days). The RCT found no significant difference between cryosurgery and conventional stripping in haematoma percentage (calculated from measurement of upper leg length, knee circumference, and thigh circumference: 51% with cryotherapy *v* 43% with conventional stripping; P value reported as not significant). The second RCT found no difference in postoperative pain between the two groups at 24 hours (measured by median pain score on 10-cm visual analogue scale: 1.8 with conventional stripping *v* 1.7 with cryostripping; P = 0.67). [33] The RCT found significantly more bruising at 1 week in the conventional stripping group compared with the cryostripping group (mean area at thigh: 161 cm^2 with conventional stripping *v* 123 cm^2 with cryostripping; P = 0.01). This RCT also showed no significant difference in paraesthesia due to saphenous nerve injury between the two groups at 1 week (P = 0.054) and 6 months (P = 0.95). One further RCT that reported on adverse effects also found no significant difference in nerve injury between groups at 1 week (12% with cryostripping *v* 12% with conventional stripping; P = 0.787; see comments). [36]

Local anaesthetic flush after conventional stripping versus conventional stripping alone:
The RCT reported that no adverse effects were found in people given the local anaesthetic flush. [34]

Stripping versus ambulatory conservative haemodynamic management of varicose veins (CHIVA)
The RCT did not report on adverse effects. [35]

Cryostripping versus endovenous laser:
See harms of endovenous laser, p 15 .

Stripping versus endovenous laser:
See harms of endovenous laser, p 15

Comment:

Avulsion versus injection sclerotherapy:
See comment under injection sclerotherapy, p 4 .

Cryostripping versus conventional stripping:
A third RCT reported quality of life outcomes in 494 people randomised to cryostripping and conventional stripping. [36] The results are not included in this review as follow-up was 67% at 6 weeks and 53% at 6 months, which is below the minimum follow-up criteria for this *Clinical Evidence* review.

Stripping versus ambulatory conservative haemodynamic management of varicose veins (CHIVA):
The RCT found that stripping led to a higher ultrasound documented recurrence rate compared with CHIVA at 10 years (OR 2.2, 95% CI 1 to 5; P = 0.04). [35]

Clinical guide:
Most clinicians previously believed that saphenofemoral ligation, stripping to the knee, plus avulsion was the first-line treatment for primary great saphenous varicose veins. Newer treatments for varicose veins such as foam sclerotherapy, radiofrequency ablation, and endovenous laser have started to challenge this assumption. There is no evidence for any benefit for powered phlebectomy over avulsions of varicose veins.

OPTION SURGERY (POWERED PHLEBECTOMY)

Symptom improvement
Compared with avulsion following ligation We don't know whether powered phlebectomy is more effective at reducing pain at 8 days or at improving cosmetic appearance at 6 weeks (low-quality evidence).

Note
We found no clinically important results about powered phlebectomy compared with no treatment or compression stockings in people with varicose veins.

For GRADE evaluation of interventions for varicose veins, see table, p 20 .

Benefits:

We found two RCTs comparing powered phlebectomy versus avulsion (conventional hook phlebectomy) following ligation. [40] [41] The first RCT found no significant difference between treatments in pain at 8 days (141 people, 188 legs randomised; pain assessed using a visual analogue scale, where 0 = no pain, and 10 = most severe pain; results presented graphically; reported as not significant; P value not reported). [40] It found no significant difference between treatments in participant satisfaction or cosmetic appearance at 6 weeks (both measured on a visual analogue scale, where 0 = "very dissatisfied" and 10 = "very satisfied"; proportion of people "satisfied": 87% with powered phlebectomy *v* 91% with avulsion; P = 0.88; mean cosmetic score: 7.44 with powered phlebectomy *v* 8.27 with avulsion, results presented graphically; P value not reported). The second RCT found that avulsion improved pain more than powered phlebectomy at 6 weeks (66 people with unilateral saphenofemoral incompetence; pain measured using a 10-cm Burford pain thermometer, scale ranging from 0 = no pain, to 100 = most severe pain imaginable; median change in Burford pain scale from baseline: –20 with avulsion *v* –2 with powered phlebectomy; P = 0.019). [41]

Harms:

Powered phlebectomy versus conventional phlebectomy:
The first RCT found no significant difference between treatments in the incidence of cellulitis, cutaneous nerve injury, or severe bruising after 2 weeks (cellulitis: 2/88 [2%] with powered phlebectomy *v* 3/100 [3%] with conventional phlebectomy; P = 0.33; cutaneous nerve injury: 16/88 [18%] with powered phlebectomy *v* 25/100 [25%] with conventional phlebectomy; P = 0.33; severe bruising: 8/88 [9%] with powered phlebectomy *v* 7/100 [7%] with conventional phlebectomy; P = 0.77). [40] The second RCT found that powered phlebectomy increased bruising and discoloration compared with avulsion at 1 week (AR: 39% with powered phlebectomy *v* 25% with avulsion; P <0.001) and 6 weeks (AR: 7% with powered phlebectomy *v* 0% with avulsion; P <0.001). [41] There was no difference between the groups in terms of cutaneous nerve injury (AR for saphenous neuropathy; at 1 week: 14% with powered phlebectomy *v* 3% with avulsion; P = 0.09; at 6 weeks: 7% with powered phlebectomy *v* 3% with avulsion; P = 0.07).

Comment:

Powered phlebectomy versus avulsion:
Both RCTs comparing powered phlebectomy versus conventional phlebectomy found that powered phlebectomy significantly reduced the number of incisions, [40] [41] but this made no difference to participant satisfaction. [40]

Clinical guide:
There is no evidence for any benefit for powered phlebectomy over avulsions of varicose veins.

OPTION RADIOFREQUENCY ABLATION

Symptom improvement
Compared with endovenous laser Radiofrequency ablation may be more effective at reducing pain and self-reported tenderness at 48 hours, 1 week, and 2 weeks, but not at 4 weeks (low-quality evidence).

Recurrence rates
Compared with stripping We don't know whether radiofrequency ablation and stripping differ in effectiveness at reducing recurrence (clinically detected) of varicose veins (low-quality evidence).

Quality of life
Compared with endovenous laser Radiofrequency ablation may be more effective than endovenous laser at improving global quality of life scores (measured by the Chronic Venous Insufficiency Quality of Life Questionnaire) at 1 week and 2 weeks, but not at 4 weeks (low-quality evidence).

For GRADE evaluation of interventions for varicose veins, see table, p 20 .

Benefits:

Radiofrequency ablation versus stripping:
We found no systematic review (see comment below). We found one RCT comparing radiofrequency ablation versus stripping. [42] The RCT (33 people with primary varicose veins) found no significant difference between radiofrequency ablation and stripping in clinical detection of recurrence of varicose veins and patient satisfaction with cosmetic result (recurrence: 33% with radiofrequency ablation *v* 15% with stripping; P = 0.4; patient satisfaction with cosmetic result: 14/15 with radiofrequency ablation *v* 12/13 with stripping; P value not reported; significance not reported). The study did not seem to perform an intention-to-treat analysis. [42]

Radiofrequency ablation versus endovenous laser:
We found one RCT in which 87 limbs in 69 people with primary great saphenous incompetence were randomised to radiofrequency ablation using the ClosureFast catheter or endovenous laser. [43] The RCT found that, compared with endovenous laser, radiofrequency ablation significantly reduced postoperative pain at 48 hours, 1 week, and 2 weeks, but found no significant difference between groups at 4 weeks (measured by visual analogue scale 0–10: 48 hours, 0.7 with radiofrequency ablation *v* 1.9 with endovenous laser; P <0.0001; 1 week: 0.2 with radiofrequency ablation *v* 1.8 with endovenous laser; P <0.0001; 2 weeks, 0.1 with radiofrequency ablation *v* 1.2 with endovenous laser; P <0.0001; 4 weeks: 0.2 with radiofrequency ablation *v* 0.4 with endovenous laser; P = 0.29). The RCT found that, compared with endovenous laser, radiofrequency ablation significantly reduced patient reported tenderness at 48 hours, 1 week, and 2 weeks but found no significant difference between groups at 4 weeks (measured by 0–10 scale, where 0 = no tenderness and 10 = severe tenderness: 48 hours: 0.9 with radiofrequency ablation *v* 2.0 with endovenous laser; P = 0.0048; 1 week: 0.5 with radiofrequency ablation *v* 1.6 with endovenous laser; P = 0.0036; 2 weeks, 0.3 with radiofrequency ablation *v* 1.2 with endovenous laser; P = 0.0005; 4 weeks: 0.3 with radiofrequency ablation *v* 0.5 with endovenous laser; P = 0.57). The RCT found that radiofrequency ablation significantly improved global quality of life scores (measured by the Chronic Venous Insufficiency Quality of Life Questionnaire) at 1 and 2 weeks compared with endovenous laser, but found no significant difference between groups at 4 weeks (1 week, P = 0.0044; 2 weeks, P = 0.045; 4 weeks, P = 0.94). Analysis was by limbs not people, and outcomes were not reported beyond 4 weeks. [43]

Harms:

Radiofrequency ablation versus stripping:
We found no systematic review (see comment below). In the RCT [42] one person who had received radiofrequency ablation reported a period of superficial thrombophlebitis. One person who received radiofrequency ablation (7%) and 5 people who received stripping (38%) reported symptoms of saphenous nerve injury. No significance testing was reported for these adverse effects.

Radiofrequency ablation versus endovenous laser:
The RCT found that radiofrequency ablation led to significantly less postoperative bruising at all measured time points compared with endovenous laser (48 hours, P <0.0001; 1 week, P <0.0001; 2 weeks, P <0.0001; 4 weeks, P = 0.005). [43] The RCT found that overall complication rate was significantly lower with radiofrequency ablation compared with endovenous laser (4.4% with radiofrequency ablation *v* 22% with endovenous laser; P = 0.021). With regard to individual adverse effects, the incidence of phlebitis (P = 0.009) and erythema (P = 0.45) was significantly higher with endovenous laser, but there was no significant difference between groups in hyperpigmentation (P >0.99), paraesthesia (indicating possible nerve injury; P = 0.06), infection (no cases), or thromboembolism/DVT (P = 0.47). [43]

Comment:

Radiofrequency ablation versus stripping:
We found one systematic review (search date 2004), which identified two RCTs comparing radiofrequency ablation versus stripping of the long saphenous vein following saphenofemoral ligation in people with complicated varicose veins. [44] The review did not meet inclusion criteria for this topic because of population definition. The review did not perform a meta-analysis and the RCTs were considered to be of poor quality: assessors were not blind to treatment, methods of randomisation were unclear, and analyses were not by intention to treat. Both RCTs found that radiofrequency ablation significantly reduced postoperative pain compared with stripping, but found inconclusive evidence about the effects of radiofrequency ablation on quality of life outcomes. Subsequent data from one of these RCTs showed improved quality of life in the radiofrequency ablation group at 1 and 2 years. [45] We found one further systematic review (search date 2007), which included a meta-analysis of 8 studies; these were not all RCTs and therefore this review has not been reported further. [46] One further high-quality RCT comparing radiofrequency ablation to stripping was published after the search date for this systematic review and will be assessed for inclusion in a subsequent update. [47]

Endovenous procedures (radiofrequency ablation and endovenous laser) are increasingly used in mainstream clinical practice, and further evidence comparing them with other active treatments is emerging.

OPTION ENDOVENOUS LASER

Symptom improvement
Compared with cryostripping Endovenous laser may be more effective than cryostripping at reducing pain scores (measured by visual analogue scale) at 10 days. We don't know whether endovenous laser is more effective than cryostripping at improving outcomes measured by the Venous Clinical Severity Score at 6 months to 2 years (low-quality evidence).

Compared with stripping We don't know whether endovenous laser is more effective than saphenofemoral ligation plus stripping plus avulsions at improving pain, cosmetic appearance, or outcomes measured by the Venous Clinical Severity Score between 7 days and 6 months (low-quality evidence).

Compared with radiofrequency ablation Endovenous laser may be less effective than radiofrequency ablation at reducing pain and self-reported tenderness at 48 hours, 1 week, and 2 weeks, but not at 4 weeks (low-quality evidence).

Quality of life
Compared with cryostripping We don't know whether endovenous laser is more effective than cryostripping at improving quality of life scores (as measured by the Aberdeen Varicose Vein Symptom Score) at 6 months to 2 years (low-quality evidence).

Compared with stripping We don't know whether endovenous laser is more effective than saphenofemoral ligation plus stripping plus avulsions at improving quality of life scores (measured by the Chronic Venous Insufficiency Quality of Life Questionnaire or the Aberdeen Varicose Vein Symptom Score) at 4 weeks to 6 months (low-quality evidence).

Compared with radiofrequency ablation Endovenous laser may be less effective than radiofrequency ablation at improving global quality of life scores (measured by the Chronic Venous Insufficiency Quality of Life Questionnaire) at 1 week and 2 weeks, but not at 4 weeks (low-quality evidence).

For GRADE evaluation of interventions for varicose veins, see table, p 20 .

Benefits:

Endovenous laser versus cryostripping:
We found one RCT (120 people), which compared endovenous laser ablation (EVLA) versus cryostripping. [37] The RCT reported that neither the participants nor investigators could be blinded to the treatments used. The RCT found that endovenous laser significantly reduced pain scores compared with cryostripping at 10 days (measured by visual analogue scale 0–10: 2.9 with EVLA *v* 4.4 with cryostripping; P = 0.003). The RCT found no significant difference between EVLA and cryostripping in outcomes as measured by the Venous Clinical Severity Score (VCSS) or Aberdeen Varicose Vein Symptom Score (AVVSS; a disease-specific quality of life measure) over 2 years (measured at 6 months, 12 months, and 2 years: VCSS, P = 0.561; AVVSS, P = 0.064; multivariate linear modelling over 2-year time period). [37]

Endovenous laser versus stripping:
We found two RCTs comparing EVLA with stripping (see comment below). [38] [39] The first RCT (100 people with great saphenous incompetence) compared saphenofemoral ligation plus stripping plus avulsions versus endovenous laser. [38] The RCT found no significant difference between endovenous laser and stripping in participant-reported cosmetic appearance at 16 weeks (measured

in 5 categories from very good to very poor, P = 0.56) or in quality of life scores at 4 weeks (assessed by the Chronic Venous Insufficiency Quality of Life Questionnaire [global score]: –1.3 with EVLA *v* +4.4 with stripping; P = 0.342). There was also no significant difference between groups in pain at 7 or 28 days (visual analogue scale 10-cm scale, median: 7 days: 2.13 with EVLA *v* 2.52 with stripping; P = 0.56; 28 days: 0.51 with EVLA *v* 0.55 with stripping; P = 0.88). [38]

The second RCT (121 people [137 legs]) compared endovenous laser versus saphenofemoral ligation plus stripping plus avulsions; all procedures were performed under local anaesthetic with sedation if required. [39] The RCT performed an intention-to-treat analysis. The level of blinding at assessment was not reported. The RCT reported that symptom scores as measured by VCSS did not differ between groups at any time point (baseline: 2.8 with EVLA *v* 2.4 with stripping; 3 months: 0.1 with EVLA *v* 0.2 with stripping; 6 months: 0.4 with EVLA *v* 0.2 with stripping; statistical analysis between groups not reported). It reported that there was no difference in quality of life outcomes as measured by the AVVSS (baseline: 18.6 with EVLA *v* 16.1 with stripping; 3 months: 6.9 with EVLA *v* 8.2 with stripping; 6 months: 7.1 with EVLA *v* 5.3 with stripping; statistical analysis between groups not reported). The RCT reported that there was a significantly higher score as measured by the Bodily Pain domain of the short-form [SF]-36 questionnaire in the surgery group as compared with the endovenous laser group (results presented graphically; P <0.05). [39]

Endovenous laser versus radiofrequency ablation:
See benefits of radiofrequency ablation, p 14 .

Harms:

Endovenous laser versus cryostripping:
The RCT found no significant difference between endovenous laser and cryostripping in rates of DVT (no cases in either group), superficial thrombophlebitis (P = 0.74), bruising (P = 1.0), or saphenous neuropathy (P = 1.0) at 10 days. [37] Skin tightening was significantly more common with endovenous laser (17/60 [28%] with endovenous laser *v* 0/60 [0%] with cryostripping; P <0.001), whereas induration was significantly more common with cryostripping (9/60 [15%] with endovenous laser *v* 31/60 [52%] with cryostripping; P <0.001). [37]

Endovenous laser versus stripping:
The first RCT found that EVLA significantly reduced haematoma formation compared with stripping at 1 week (median: 125 cm^2 with EVLA *v* 200 cm^2 with stripping; P = 0.001). [38] The second RCT found significantly more bruising with stripping compared with endovenous laser at 12 days (25% people with stripping *v* 11% people with EVLA; P <0.05). [39]

Endovenous laser versus radiofrequency ablation:
See harms of radiofrequency ablation, p 14 .

Comment:

We found one further RCT (118 people, 136 legs), which compared saphenofemoral ligation, stripping, and avulsions; EVLA using stepwise laser withdrawal; and EVLA using continuous laser withdrawal. [48] However, follow-up was less than 80%, which is below the minimum for inclusion in this *Clinical Evidence* review.

Endovenous procedures (endovenous laser and radiofrequency ablation) are increasingly used in mainstream clinical practice, and further evidence comparing them with other active treatments is emerging.

OPTION SELF-HELP (EXERCISE, DIET, ELEVATION OF LEGS, AVOIDANCE OF TIGHT CLOTHING, ADVICE)

We found no clinically important results about self-help measures (exercise, diet, leg elevation, avoidance of tight clothing) compared with no treatment (watchful waiting) in people with varicose veins.

For GRADE evaluation of interventions for varicose veins, see table, p 20 .

Benefits: We found no systematic review or RCTs.

Harms: We found no RCTs.

Comment:

Clinical guide:
We found no RCT evidence for self-help measures for treating varicose veins. Most clinicians would advise on weight loss (if overweight), regular exercise, avoidance of prolonged standing, and elevation of the legs to alleviate symptoms of varicose veins.

GLOSSARY

Avulsion (phlebectomy) Used to treat multiple varicosities after saphenofemoral or saphenopopliteal ligation or in people with perforator incompetence. Small incisions are made in the skin overlying each varicosity and the affected vein interrupted or excised using either a vein hook or forceps.

Foam sclerotherapy A new technique in which a standard sclerosant is mixed with air to create a foam. This is then injected into the varicosities under ultrasound guidance.

Ligation Involves tying off a vein close to the site of incompetence to prevent blood flowing from the deep to the superficial system.

Powered phlebectomy Involves infiltrating subcutaneous tissues with a saline solution containing local anaesthetic (lidocaine) and dilute epinephrine (adrenaline). A mechanical device is then introduced. This has a blade that rotates at 800–1000 rpm, destroying the varicose vein. Vein fragments are removed by suction connected to the device.

Urticaria (hives) is the presence of itchy, raised patches of skin (wheals), which may be due to certain foods or drugs, as well as other factors including stress. The condition may be acute or chronic.

Cryostripping (cryosurgery) Involves introducing a cryoprobe into the long saphenous vein following saphenofemoral ligation. The probe is cooled to –85 °C using NO_2 or CO_2. This causes the vein to freeze to the probe and this is then removed, stripping the vein.

Ecchymosis This is a small, rounded, or irregular blue or purple patch caused by a small haemorrhage in the skin or mucous membrane.

Endovenous laser A new technique involving the introduction of a catheter into the greater or lesser saphenous vein under ultrasound guidance. This delivers laser energy that heats the saphenous vein, thereby sealing the lumen.

Great saphenous vein is also known as the long saphenous vein.

Low-quality evidence Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Moderate-quality evidence Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Radiofrequency ablation A new technique involving the introduction of a catheter into the greater or lesser saphenous vein under ultrasound guidance. This delivers radiofrequency energy which heats the saphenous vein, thereby sealing the lumen.

Sclerosant An injected solution that displaces blood from the vein causing inflammation of the vein wall and occlusion. Commonly used sclerosants include sodium tetradecyl sulphate (sotradecol) and polidocanol (also called aetoxysclerol, aethoxysclerol, aethoxyskerol, or hydroxypolyaethoxydodecan).

Short saphenous vein is also known as lesser saphenous vein.

Stripping A wire, plastic, or metal rod is passed through the lumen of the saphenous vein and is used to strip the entire vein out of the leg. This disconnects any superficial veins from the deep venous system. Inversion stripping is a newer technique in which the vein is inverted upon itself after stripping.

Telangiectasia Dilated superficial blood vessels in the skin. This is often synonymous with the term "thread veins" or "spider veins".

Very low-quality evidence Any estimate of effect is very uncertain.

SUBSTANTIVE CHANGES

Compression stockings New evidence added. [9] Categorisation unchanged (Unknown effectiveness) as there remains insufficient evidence to judge the effects of this intervention.

Endovenous laser New evidence added. [43] [37] [38] [48] [39] Categorisation unchanged (Unknown effectiveness) as there remains insufficient evidence to judge the effects of this intervention.

Radiofrequency ablation New evidence added. [43] Categorisation unchanged (Unknown effectiveness) as there remains insufficient evidence to judge the effects of this intervention.

Surgery (stripping) New evidence added. [33] [35] [36] [37] [38] [39] [20] Categorisation unchanged (Likely to be beneficial).

Injection sclerotherapy New evidence added. [20] [25] Categorisation changed from Unknown effectiveness to Likely to be beneficial.

Surgery (powered phlebectomy) Evidence reassessed. Categorisation changed from Trade-off between benefits and harms to Unknown effectiveness as there is insufficient RCT evidence to judge the effects of this intervention.

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Competing interests: PVT is the main author of one systematic review referenced in this review.

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TABLE **GRADE evaluation of interventions for varicose veins**

Important outcomes	**Symptom improvement, recurrence rates, quality of life, adverse effects**								
Number of studies (participants)	**Outcome**	**Comparison**	**Type of evidence**	**Quality**	**Consistency**	**Directness**	**Effect size**	**GRADE**	**Comment**
What are the effects of treatments in adults with varicose veins?									
3 (229) [9] [10]	Symptom improvement	Compression stockings *v* no treatment	4	−3	0	0	0	Very low	Quality points deducted for incomplete reporting of results, weak methods (randomisation, allocation concealment, blinding), no intention-to-treat analysis in 2 RCTs, and unclear washout period in 1 crossover RCT
1 (34) [11]	Symptom improvement	Injection sclerotherapy *v* no treatment/conservative treatment	4	−1	−1	−1	0	Very low	Quality point deducted for sparse data. Consistency point deducted for no consistent benefit. Directness point deducted for uncertainty about number of participants following co-intervention advice
1 (101) [1]	Symptom improvement	Injection sclerotherapy *v* compression stockings	4	−1	0	0	0	Moderate	Quality point deducted for sparse data
3 (at least 246 people) [17] [14] [16]	Recurrence rates	Injection sclerotherapy *v* surgery	4	−3	0	−1	0	Very low	Quality points deducted for incomplete reporting of results and methodological weaknesses. Directness point deducted for disease severities and treatment differences between groups
1 (516) [18]	Symptom improvement	Sclerotherapy plus ligation *v* conventional surgery or sclerotherapy alone	4	−1	0	0	0	Moderate	Quality point deducted for incomplete reporting of results
1 (156) [19]	Symptom improvement	Sclerotherapy plus ligation *v* stripping plus ligation	4	−1	0	0	0	Moderate	Quality point deducted for sparse data
1 (82) [20]	Symptom improvement	Foam sclerotherapy plus saphenofemoral ligation *v* saphenofemoral ligation plus stripping plus avulsion or conventional stripping/invagination stripping	4	−3	0	0	0	Very low	Quality points deducted for sparse data, incomplete reporting of results, and results for 2 groups combined in analysis
1 (60) [13]	Quality of life	Foam sclerotherapy plus saphenofemoral ligation *v* saphenofemoral ligation plus stripping plus avulsion or conventional stripping/invagination stripping	4	−1	0	0	0	Moderate	Quality point deducted for sparse data
2 (1709) [21] [22]	Symptom improvement	Different types of sclerosant *v* each other	4	−1	0	−2	0	Very low	Quality point deducted for weak methods (unclear randomisation, allocation concealment, level of blinding). Directness points deducted for no statistical comparison between groups and unclear outcome assessment
1 (887) [17]	Recurrence rates	Foam sclerotherapy *v* conventional sclerotherapy	4	−1	0	0	0	Moderate	Quality point deducted for incomplete reporting of results
2 (169) [26] [27]	Symptom improvement	Avulsion plus stripping *v* avulsion alone	4	−1	−1	0	0	Low	Quality point deducted for sparse data. Consistency point deducted for conflicting results

Important outcomes	Symptom improvement, recurrence rates, quality of life, adverse effects								
Number of studies (participants)	Outcome	Comparison	Type of evidence	Quality	Consistency	Directness	Effect size	GRADE	Comment
2 (169) [26] [27]	Recurrence rates	Avulsion plus stripping *v* avulsion alone	4	−1	−1	0	0	Low	Quality point deducted for sparse data. Consistency point deducted for conflicting results
1 (80) [29]	Symptom improvement	Stripping *v* sequential avulsion	4	−2	0	0	0	Low	Quality points deducted for sparse data and incomplete reporting of results
1 (163) [30]	Symptom improvement	Partial stripping *v* total stripping	4	−2	0	−1	0	Very low	Quality points deducted for sparse data and incomplete reporting of results. Directness point deducted for unclear measurement of outcome assessed
1 (30) [31]	Symptom improvement	Inversion stripping *v* conventional stripping	4	−1	0	0	0	Moderate	Quality point deducted for sparse data
1 (40) [32]	Symptom improvement	Cryostripping *v* conventional stripping	4	−2	0	0	0	Low	Quality points deducted for sparse data and incomplete reporting of results
1 (146) [33]	Quality of life	Cryostripping *v* conventional stripping	4	−3	0	0	0	Very low	Quality points deducted for sparse data, incomplete reporting of results, 8 people selectively excluded from analysis, and no intention-to-treat analysis
1 (100) [34]	Symptom improvement	Local anaesthetic flush after conventional stripping *v* conventional stripping alone	4	−1	0	0	0	Moderate	Quality point deducted for sparse data
1 (124) [35]	Symptom improvement	Stripping *v* ambulatory conservative haemodynamic management of varicose veins (CHIVA)	4	−2	0	0	0	Low	Quality points deducted for sparse data and no intention to treat analysis
2 (207) [40] [41]	Symptom improvement	Powered phlebectomy *v* avulsion following ligation	4	−1	−1	0	0	Low	Quality point deducted for incomplete reporting of results. Consistency point deducted for conflicting results
1 (28) [42]	Recurrence rates	Radiofrequency ablation *v* stripping	4	−2	0	0	0	Low	Quality points deducted for sparse data and no intention-to-treat analysis
1 (69) [43]	Symptom improvement	Radiofrequency ablation *v* endovenous laser	4	−1	0	−1	0	Low	Quality point deducted for sparse data. Directness point deducted for short-term follow-up
1 (69) [43]	Quality of life	Radiofrequency ablation *v* endovenous laser	4	−1	0	−1	0	Low	Quality point deducted for sparse data. Directness point deducted for short-term follow-up
1 (120) [37]	Symptom improvement	Endovenous laser *v* cryostripping	4	−2	0	0	0	Low	Quality points deducted for sparse data and lack of blinding
1 (120) [37]	Quality of life	Endovenous laser *v* cryostripping	4	−2	0	0	0	Low	Quality points deducted for sparse data and lack of blinding
2 (221) [38] [39]	Symptom improvement	Endovenous laser *v* stripping	4	−2	0	0	0	Low	Quality points deducted for unclear blinding and incomplete reporting of results in 1 RCT
2 (221) [38] [39]	Quality of life	Endovenous laser *v* stripping	4	−2	0	0	0	Low	Quality points deducted for unclear blinding and incomplete reporting of results in 1 RCT

Important out-comes	**Symptom improvement, recurrence rates, quality of life, adverse effects**								
Number of studies (participants)	**Outcome**	**Comparison**	**Type of evi-dence**	**Quality**	**Con-sisten-cy**	**Direct-ness**	**Effect size**	**GRADE**	**Comment**

Type of evidence: 4 = RCT Consistency: similarity of results across studies.
Directness: generalisability of population or outcomes.
Effect size: based on relative risk or odds ratio.